IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION MDL No. 2187

THIS DOCUMENT RELATES TO C. R. BARD WAVE 4 & WAVE 5 CASES BEFORE JUDGE GOODWIN:

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Michael D. Vardy, M.D.)

The plaintiffs filed their Notice of Adoption of Prior Daubert Motion of Michael D. Vardy, M.D. for Waves 4 and 5 Cases ("Notice") [ECF No. 4552] in *In re C. R. Bard, Inc.*, *2:10-md-2187*, MDL 2187, on September 27, 2017. The plaintiffs attached as exhibits to their Notice a motion [ECF No. 4552-1], memorandum in support [ECF No. 4552-2], and reply brief [ECF 4552-3], which plaintiffs seek to adopt and incorporate as their briefing for Waves 4 and 5. The defendant also adopted and incorporated by Notice of Adoption of C.R. Bard, Inc.'s Prior Memorandum of Law in Opposition to Plaintiffs' Motion to Exclude Certain General Opinions and Testimony of Michael D. Vardy, M.D., for Wave 4 and Wave 5 Cases, a brief in response to the plaintiffs' Notice. [ECF No. 4649]. The court construes the plaintiffs' Notice as a motion. As such, the Notice is now ripe for consideration because the briefing is complete. As set forth below, the plaintiffs' motion is **GRANTED in part** and **DENIED in part**.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 16,000 cases currently pending, approximately 1,500 of which are in the Bard MDL, 2187 MDL.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict Litigation in Products Liability Cases* 3 (2011). In an effort to manage the massive Bard MDL efficiently and effectively, the court decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, a docket control order subjects each case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order ("PTO") # 236 (establishing Wave 4); PTO # 244 (establishing Wave 5). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure for cases designated in Wave 4 and Wave 5. The court instructed the parties to file briefing on general causation issues

in the main MDL, MDL 2187, while specific causation *Daubert* motions, responses, and replies were to be filed in the individual member cases. To the extent that an expert is both a general and specific causation expert, the court advised the parties that they could file a general causation motion in the main MDL and a specific causation motion in an individual member case. *See* PTO # 236, at 4; PTO # 244, at 4.

Before plunging into the heart of the motion, and to clarify the record, I am compelled to comment on the manner in which the parties filed the instant *Daubert* motion and response in opposition. Similar to other *Dauberts* filed in the main MDL, the plaintiffs filed the instant motion as a "Notice," adopting and incorporating the entirety of a motion and its corresponding papers filed in a previous case before the court. Defendant C. R. Bard, Inc. ("Bard"), likewise, filed its opposing briefs in conjunction with a similar "Notice." The parties then attached the substance of their briefs, i.e., the supporting or opposing memorandum of law, as an exhibit to their respective Notice. So, for example, the plaintiffs attach the memorandum in support of their *Daubert* motion as "Exhibit 1" to their Notice. The plaintiffs also integrate into Exhibit 1 vital supporting papers, such as the expert report demarcated rather confusingly within Exhibit 1 as "Exhibit 1," as well as other papers, forming one large document. With this in mind, the court turns its attention to the present dispute.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and

(1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods" which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. However, he or she must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court is the gatekeeper. It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading"; the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I "need not determine that the proffered expert testimony is irrefutable or certainly correct" – "[a]s with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (quoting *Daubert*, 509 U.S. at 596 (alteration in original)); *see also Md. Cas. Co.*, 137 F.3d at 783 ("All *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful.").

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" (citation omitted)); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's "helpfulness"

> standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted). At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

III. Discussion

Dr. Michael D. Vardy is an urogynecologist who performs prolapse and incontinence procedures using various treatment options, including transvaginal mesh. Bard offers Dr. Vardy as an expert on the operation and use of the Align. The plaintiffs move to exclude three of Dr. Vardy's opinions: (1) opinions regarding mesh shrinkage or contracture; (2) opinions on the degradation of polypropylene; and (3) opinions regarding the Material Safety Data Sheet ("MSDS") for the polypropylene material used to manufacture Bard's pelvic repair mesh products.

A. Opinions on Mesh Shrinkage

The plaintiffs object to Dr. Vardy's opinion that mesh does not shrink because, in their view, the opinion lacks a sufficient reliable basis. Specifically, the plaintiffs contend "the entirety of the factual basis for [this] opinion is Dr. Vardy's statement that he has not personally seen evidence of mesh shrinkage, that if shrinkage occurred one would expect that more slings would have to be removed because of urinary retention, [and] one article that he has reviewed did not find mesh shrinkage." Pls.' Mot. to Exclude Certain Gen. Ops. & Test. of Michael D. Vardy, M.D. & Br. in Supp. ("Pls.' Mot. re: Vardy"), at 2 [ECF No. 4552-1]. Moreover, the plaintiffs point out that Dr. Vardy "absolutely fails to mention or account for the numerous

peer-reviewed and published articles that establish mesh shrinkage." *Id.* at 5. In response, Bard insists that Dr. Vardy's experience with implanting transvaginal mesh and his review of two articles provide a reliable basis for his opinion on mesh shrinkage.

The reliability of an expert's opinion comes into question when he has not acknowledged or accounted for science that refutes his position. *See, e.g.*, *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) ("[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable."). While it claims that Dr. Vardy has reviewed two articles that, in its view, are favorable to his opinion, Bard provides no indication – and the court cannot find any in the record – that Dr. Vardy considered any identifiable contrary scientific evidence in the consideration of his opinion. Indeed, Dr. Vardy appears to have wholly ignored data showing mesh shrinkage:

> Q: Please turn to the last page of [the Bard memo from Bobby Orr]. Are you familiar with any of these publications that are listed on the last page of this memo?
>
> A: I'm looking over all of them here. A couple of them look familiar, yes.
>
> Q: Are you familiar with William Cobb . . . Do you know who he is?
>
> A: No . . . .
>
> Q: Have you heard of the name Dr. Klinge?
>
> A: Sounds like a European study so I don't think I know him personally.

> Q: What about FH Greca, have you heard that name before?
>
> A: No.
>
> Q: Have you heard of Thomas Gilbert?
>
> A: Name sounds familiar, but not definitively.
>
> Q: Have you heard of Dr. Klosterhalfen?
>
> A: No.

Def.'s Mem. of Law in Opp'n to Pls.' Mot. to Exclude Certain General Ops. & Test. of Michael D. Vardy, M.D., Ex. 2 ("Vardy Dep."), at 207:17 – 208:16 [ECF No. 4649-2]; *see also Id.* at 206:3 – 209:1 (testifying that he is not familiar with several studies that found mesh shrinkage).

Therefore, regardless of Dr. Vardy's experience with mesh implantation, his complete failure to explain his disagreement with refuting literature, or even account for it, is decisive. *See, e.g.*, *Abarca v. Franklin Cnty. Water Dist.*, 761 F. Supp. 2d 1007, 1066 n.60 (E.D. Ca. 2011) ("A scientist might well pick data from many different sources to serve as circumstantial evidence for a particular hypothesis, but a reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted."); *Rimbert v. Eli Lilly & Co.*, CIV 06-0874 JCH/LFG, 2009 WL 2208570, at *14 n.19 (D.N.M. July 21, 2009) *aff'd*, 647 F.3d 1247 (10th Cir. 2011) ("[A]n expert who chooses to completely ignore significant contrary epidemiological evidence in favor of focusing solely on non-epidemiological studies that support her conclusion

engages in a methodology that courts find unreliable."). Therefore, the plaintiffs' motion on this point is **GRANTED** and this opinion is **EXCLUDED**.

B. Opinions on Degradation

Next, the plaintiffs object to the following statement in Dr. Vardy's expert report: "I am not aware of any medical literature or scientific information to support the theory polypropylene is not suitable for permanent implant in humans or that it degrades as a result of either oxygen or peroxides in the body or intraoperative contact, however minimal, with Betadine." Pls.' Mot. re: Vardy, Ex. 1 ("Dr. Vardy's Expert Report"), at 12 [ECF No. 4552-1]. In short, the plaintiffs argue that this opinion is unreliable because, according to them, multiple scientific studies refute his conclusions, including a number of the studies Dr. Vardy reported as supporting evidence. In response, Bard argues that the studies put forth by the plaintiffs are inconclusive and indecisive compared to Dr. Vardy's more focused opinion that there is no reliable evidence of a "*clinical* impact" on patients, which they argue is a materially different opinion from the studies reporting on polypropylene mesh under a scanning electron microscope identified by the plaintiffs. *See* Def.'s Mem. of Law in Opp'n to Pls.' Mot. to Exclude Certain General Ops. & Test. of Michael D. Vardy, M.D., at 7 [ECF No. 4649-2] ("Dr. Vardy's opinion is that there is no reliable evidence of such a clinical impact.").

Under *Daubert,* the court is not to decide whether an opinion is scientifically correct; it is to evaluate the method a proffered expert uses in reaching that opinion. *Daubert*, 509 U.S. at 595 ("The focus, of course, must be solely on principles

and methodology, not on the conclusions that they generate."). Here, the plaintiffs focus their arguments on why Dr. Vardy's ultimate conclusion—that any degradation *in vivo* does not have a clinical impact—is wrong according to other sources. To the extent that the plaintiffs find Dr. Vardy's opinions to be incorrect or otherwise lacking, it may attack them via cross-examination. *See id.* at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

Moreover, the plaintiffs' argument that Dr. Vardy's opinion is unreliable because he failed to account for this contrary literature is unavailing. In arguing this, the plaintiffs refer to parts of my *Daubert* opinion in *Tyree*. *See Tyree et al. v. Bos. Sci. Corp.*, No. 2:12-cv-08633, 2014 WL 5320566, at *7 (S.D. W. Va. Oct. 17, 2014). In *Tyree,* the challenging party cited particular portions of the expert's deposition testimony where he was asked about specific studies contrary to his opinion and, then, dismissed them in a conclusory manner without scientific basis. Here, the plaintiffs point to no such testimony. The mere statement in Dr. Vardy's report that he is "not aware" of any medical literature or scientific information to support the theory polypropylene is not suitable for permanent implant in humans is hardly equivalent, especially in light of the plaintiffs' failure to address these purported deficiencies during their deposition of Dr. Vardy.

Therefore, the plaintiffs' motion on this point is **DENIED**.

C. Opinions on the MSDS

Finally, the plaintiffs move to exclude Dr. Vardy's opinion related to the MSDS. Dr. Vardy's opinion, in short, is that he has "seen no evidence that there is any scientific basis supporting the medical application caution language in the MSDS." Dr. Vardy's Expert Report, at 13. *Daubert* bars expert testimony based on "belief or speculation." *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999). Dr. Vardy, who has no knowledge about a manufacturer's considerations when drafting an MSDS, attempts to opine that because he did not see any evidence suggesting the MSDS has scientific roots, none exists. Such a speculative leap is improper for expert testimony. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."). Therefore, the plaintiffs' motion on this point is **GRANTED** and this opinion is **EXCLUDED**.

IV. Conclusion

For the reasons stated above, the court **ORDERS** that the plaintiffs' Notice of Adoption of Prior Daubert Motion of Michael D. Vardy, M.D. for Waves 4 and 5 Cases [ECF No. 4552], which the court has construed as a motion, is **GRANTED in part** and **DENIED in part**.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:10-md-2187, and the Bard Wave 4 and Wave 5 cases identified in the Exhibit attached hereto. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: September 5, 2018

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

Exhibit A

CIVIL ACTION NUMBER	Case Name
2:14-cv-03439	Kitchen v. C. R. Bard, Inc. et al.
2:14-cv-18890	McManus v. C. R. Bard, Inc. et al.
2:14-cv-21874	McCray v. C. R. Bard, Inc. et al.
2:14-cv-23401	Barber v. C. R. Bard, Inc. et al.
2:14-cv-28943	Smith et al. v. C. R. Bard, Inc. et al.
2:16-cv-01855	Eiffler v. Sofradim Production SAS et al.